K091796

JUL 31 2009

Appendix D
PREMARKET NOTIFICATION [510(k)] Summary

510(K) Summary of Safety and Effectiveness

Premarket Notification 510(k)

Zap Lasers, LLC
2621-B Pleasant Hill Road
Pleasant Hill, Ca. 94523

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: ***SoftLase Pro/OrthoLase/HygieneLase family of products***
Common Name(s): Surgical Laser System
Classification Name(s): Laser, Surgical

2. Establishment Name & Registration Number:

Name: Zap Lasers, LLC
Number: 3005212363

3. Classification(s):

§878.4810 **Laser surgical instrument for use in general and plastic surgery and in dermatology.**
(a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: General and Plastic Surgery & Others
Product Code(s): GEX

4. Section 514 Compliance

Zap Lasers, LLC intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, and 520 of the Food, Drug, and Cosmetic Act.

5. Performance Standards

United States Food and Drug Administration mandated performance standards for this device exist and are provided under Sections 21 CFR 1010 & 1020, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with IEC60601-1:1995+A1+A2, IEC60601-2-22:1995, and IEC60825-1:1993+A1+A2. In addition, various voluntary performance standards are utilized. Voluntary standards utilized include Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and cGMP & ISO 9000 series quality regulations.

6. Special Controls:

All Class II devices are subject to Special Controls.

7. Labeling:

The laser system discussed in this premarket notification will be manufactured by Zap Lasers, LLC and labeled as such. Zap Lasers, LLC will market the system exclusively to healthcare facilities, physicians and dentists. In addition to the usual package and identification labeling, the following additional Warnings, Cautions & Precautions statements are displayed as appropriate on or within the device packaging. They are repeated here for ease of use.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician or dentist only.

9. Predicate Device *(legally marketed comparison device)*

Zap Lasers, Inc. believes that the following surgical laser systems are substantially equivalent to the ***SoftLase Pro/OrthoLase/HygieneLase Family of products*** surgical diode system.

1. SoftLase G2 (K021227, Zap Lasers, LLC)
2. ODYSSEY NAVIGATOR (K062258, Ivoclar Vivadent, Inc.)
3. STYLA MICROLASER/STYLAORTHO Diode Laser System (K081214, Zap Lasers LLC.)

10. Summary of Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The ***SoftLase Pro ™/OrthoLase™/HygieneLase™ family of products*** intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the ***SoftLase Pro ™/OrthoLase™/HygieneLase™ family of products*** are similar to those of the cleared SoftLase G2, Odyssey Navigator and the Styla MicroLase.
- Laser output values of the ***SoftLase Pro ™/OrthoLase™/HygieneLase™ family of products*** are well within previously cleared values of the predicate dental laser system as described.
- The predicate devices and other previously cleared laser systems with similar power outputs have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the ***SoftLase Pro/OrthoLase/HygieneLase Family of products*** is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ZAP LASERS, LLC
% Mr. Jay Goble, DDS
President
2621-B Pleasant Hill Road
Pleasant Hill, California 94523

JUL 31 2009

Re: K091796
Trade/Device Name: Softlase Pro™/OrthoLase™/HygieneLase™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 15, 2009
Received: July 22, 2009

Dear Mr. Goble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N.Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab 2
Indications for Use Statement

Device Name: ***SoftLase Pro™/OrthoLase™/HygieneLase™***

Indication for Use:
The SoftLase Pro™/OrthoLase™/HygieneLase™ is to provide the ability to perform intraoral soft tissue dental, general, oral maxilla-facial and cosmetic surgery. The SoftLase Pro™/OrthoLase™/HygieneLase™ is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a contact fiber optic delivery system.

The device will be used in the following areas: general and cosmetic dentistry otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, genecology, urology, opthamology and pulmonary surgery. The following are the oralpharngeal indications for use for which the device will be marketed:

-Excision and Incision Biopsies
-Hemostatic assistance
-Treatment of Apthous Ulcers
-Frenectomy
-Frenotomy
-Gingival Incision and Excision
-Gingivectomy
-Gingivoplasty
-Incising and Draining of Abscesses
-Operculectomy
-Oral Papillectomy
-Removal of Fibromas
-Soft Tissue Crown Lengthening
-Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
-Tissue retraction for Impression
-Vestibuloplasty
-Light activation of bleaching materials for teeth whitening
-Laser-assisted bleaching/whitening of teeth

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091796